APR 2 4 2002

K020289

EXHIBIT 2

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Contact: Abe van der Werf, President

January 25, 2002

510(k) Summary of Safety and Effectiveness

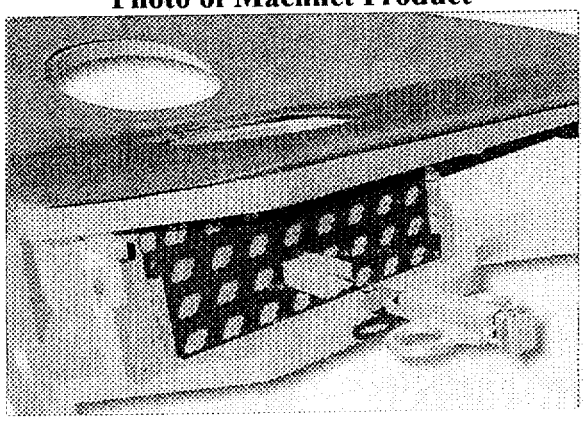
1. Identification of the Device:
   Proprietary-Trade Name: "MICS INTERVENTION AID (MICS-MIA and MICS-MIAS)."
   Classification Name: Accessory to Magnetic Resonance Diagnostic Device Product Code LNH, Stereotactic Localization Device
   Common/Usual Name: Accessory to MRI Device

2. Equivalent legally marketed device: This device is similar in design and identical in function to the Philips Medical Systems Stereotactic Localization Device (SLD) K000832 and MRI Devices Corp Model MR-Biopsy 160, K010570, and Siemens Medical Systems MR Breast Biopsy Device K010773

3. Indications for Use (intended use):. For use in conjunction with a Magnetic Resonance Scanner and the Machnet Bilateral Open Breast Coil to localize lesions in female breasts and perform needle biopsies accurately. For use by a trained physician.

4. Description of the device: The MR-Mammography Intervention Aid basically consists of a transparent acrylic plate containing about 600 puncture holes of 4 mm in diameter, held in a frame containing a set of MR fiduciary markers. The device can easily and firmly be attached to the Bilateral Open Breast Coil, thereby positioning and compressing the breast against a Breast Support Pad. The device comes with a (blue) Sliding Locator Plate for easy eye-retrieval of the software-established puncture hole, a detachable Fiduciary Marker Plate and sterilizable Needle Guide. The Mammography Intervention Aid comes with a PC-software package for supporting the calculation of the location and depth of puncturing. Information regarding the coordinates of a lesion and of the MR fiduciary markers should be retrieved from a relevant MR image and are input to the MICS software package. The software may calculate which hole to puncture through and how deep. A notebook PC with MIA Software Package installed is a system option

Photo of Machnet Product



5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	Philips Medical Systems Stereotactic Localization Device (SLD) K000832 and MRI Devices Corp Model MR-Biopsy 160, K010570, and Siemens Medical Systems MR Breast Biopsy Device K010773	MICS INTERVENTION AID (MICS-MIA and MICS-MIAS
Indications for use	For use in conjunction with a Magnetic Resonance Scanner to localize lesions in female breasts and perform needle biopsies accurately	SAME
Use with MRI Model	Philips, GE, Siemens GE Signa® :(3X-LX) 1.5T, 1.0T, 0.5T MR scanners	GE Signa :(3X-LX) 1.5T, 1.0T, 0.5T MR scanners

6. Testing information and Conclusion
   In all material respects, the "MICS INTERVENTION AID (MICS-MIA and MICS-MIAS) is substantially equivalent to Philips Medical Systems Stereotactic Localization Device (SLD) K000832 and MRI Devices Corp Model MR-Biopsy 160, K010570, and Siemens Medical Systems MR Breast Biopsy Device K010773. Testing was performed according to internal company procedures. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2002

Machnet BV
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K020289
Trade/Device Name: MICS Intervention Aid,
Catalog # MICS-MIA and MICS-MIAS
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: March 18, 2002
Received: March 19, 2002

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K020289

The "MICS INTERVENTION AID (MICS-MIA and MICS-MIAS)" is for use in conjunction with a Magnetic Resonance Scanner and the Machnet Bilateral Open Breast Coil to localize lesions in female breasts and perform needle biopsies accurately. For use by a trained physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020289